

## Original Article

# Short and Mid-term Outcome of Radiofrequency Ablation without Concomitant Phlebectomy/ Sclerotherapy for Tributary Varicose Veins

Toshihiro Kawahira, MD, PhD,<sup>1</sup> Fumihiro Miyashita, MD, PhD,<sup>1</sup> Eiji Hitomi, MD, PhD,<sup>2</sup> Masahide Enomoto, MD, PhD,<sup>3</sup> Yasuo Kondo, MD, PhD,<sup>3</sup> Masanori Morimoto, MD, PhD,<sup>3</sup> Naoshi Minamidate, MD, PhD,<sup>3</sup> Noriyuki Takashima, MD, PhD,<sup>3</sup> and Tomoaki Suzuki, MD, PhD<sup>3</sup>

Endovenous surgery in the treatment of varicose veins generally consists of laser or radiofrequency ablation (RFA) as endovenous thermal ablation (ETA) with a phlebectomy or foam sclerotherapy of tributary varicose veins to improve symptomatic or cosmetic problems. Nevertheless, the efficacy of their concomitant treatments is still controversial for a decade. In the guidelines of the Japanese Society of Phlebology, concomitant phlebectomy of tributary varicose veins with ETA is described that it is not recommended officially. In our hospital, RFA without concomitant phlebectomy of tributary varicose veins accounts for 74% of the RFA cases and it shows a relatively higher percentage than other institutions in Japan. The data of RFA without concomitant phlebectomy of tributary varicose veins are evenly matched in RFA with concomitant treatments in our data concerning recurrence, remnants, endovenous heat-induced thrombosis (EHIT), and complications. This article provides the conclusion that it would be acceptable to perform isolated RFA compared to RFA with concomitant phlebectomy or foam sclerotherapy of tributary varicose veins in short- and mid-term periods. In addition, concomitant treatments might contribute to rapid improvement of the short-term and

better long-term outcomes, not to mention cosmetic problems that are not identified demonstrably. (This is a translation of J Jpn Coll Angiol 2022; 62: 49–54.)

**Keywords:** varicose vein, radiofrequency ablation, endovenous thermal ablation, endovenous heat-induced thrombosis, deep vein thrombosis

## Introduction

As intravascular treatment for saphenous varicose veins of lower extremities, endovenous laser ablation (EVLA) and endovenous radiofrequency ablation (RFA) were covered by national insurance in 2011 and 2014, respectively, in Japan. Given their low invasiveness and simplicity, these techniques have since become widespread. Recently, saphenous vein occlusion (adhesion) surgery using cyanoacrylate, a bio-binding agent, has also been covered by insurance, further diversifying options for treating varicose veins. Prompted by the insurance approval of ClosureFAST (Covidien Ireland Limited, Dublin, Ireland), our hospital also introduced endovenous thermal ablation (ETA) surgery with RFA regarded as the pivotal axis. In 2021, we also adopted intravascular embolization surgery using a Venaseal Closure System (Covidien Ireland Limited). We have since been providing treatment for varicose veins of the lower extremities by selecting the best possible surgical modalities while also considering the preferences of patients.

Currently, it is controversial whether it is effective to conduct phlebectomy and/or sclerotherapy for collateral varicose veins in the lower thigh during ETA surgery. In the “clinical practice guidelines for endovenous thermal ablation for varicose veins 2019” published by the Japanese Society of Phlebology, this combined procedure is listed as having “no recommendations.”<sup>1)</sup> However, many institutions, both in Japan and overseas, are performing combined operations. At our hospital, the majority (74.0%) of


<sup>1</sup>Department of Cardiovascular Surgery, Koto Memorial Hospital, Higashiohmi, Shiga, Japan

<sup>2</sup>Department of Anesthesiology, Koto Memorial Hospital, Higashiohmi, Shiga, Japan

<sup>3</sup>Department of Cardiovascular Surgery, Shiga University of Medical Science, Otsu, Shiga, Japan

Received: November 27, 2024; Accepted: November 27, 2024  
Corresponding author: Toshihiro Kawahira, MD, PhD. Department of Cardiovascular Surgery, Koto Memorial Hospital, 2-1, Hiramatsu cho, Higashiohmi, Shiga 527-0134, Japan  
Tel: +81-749-45-5000  
E-mail: tkavira928@gmail.com

This is a translation of J Jpn Coll Angiol 2022; 62: 49–54.

 This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives International license.  
©2025 The Editorial Committee of Annals of Vascular Diseases.

operations have been single RFA operations without combining phlebectomy and/or sclerotherapy. In this study, we explored and analyzed cases of recurrence, retention, and endovenous heat-induced thrombosis (EHIT). We report the results along with some discussion of the literature.

## Materials and Methods

In 6 years, from April 2015 to April 2021, our hospital treated 672 patients with saphenous varicose veins of the lower extremities (816 legs). These patients had a mean age of 66.5 years (16–93 years) and comprised 289 men and 383 women. From this patient population, 497 patients, accounting for 74.0% of all patients (642 legs; 78.7%), who had undergone single RFA surgery and could be followed up for more than 6 months, were categorized into Group A. This group had a mean age of 66.9 years and comprised 211 men and 286 women. From the same patient population, 162 patients (174 legs) who had received combined treatment with phlebectomy and/or sclerotherapy were categorized into Group B for comparison (mean age: 65.6 years; 75 men and 87 women). Regarding the CEAP classification, the old classification<sup>2)</sup> was used as the standard. The majority of patients at our hospital were clinically classified into C2, C3, C4a, and C5. The anatomical, etiological, and pathophysiological classifications were As, Ep, and Pr, respectively (Table 1).

Surgical indications and exclusion criteria were set according to the guidelines published by the Japanese Society of Phlebology and the “guidelines for endovenous treatments for varicose veins.”<sup>3)</sup> In principle, patients with subjective symptoms, such as pain and numbness, and patients with skin findings, such as pigmentation and ulceration, were included. Patients with primary varicose veins of lower extremities, where vascular ultrasound revealed significant reflux, were also included. Patients were excluded if they had a previous history of deep vein thrombosis (DVT), walking difficulty in their daily living, hemorrhagic diathesis, and predisposition to thrombotic complications such as coagulation abnormalities.

As per the above guidelines, recurrence was defined as having blood flow in a patent area exceeding 5 cm in a treated vein, having a recurrent collateral varicose vein that was macroscopically observed during postoperative follow-up, or having congestive symptoms stemming from valve incompetence in a superficial vein. Furthermore, retention was defined as a condition in which a varicose vein that had been noted preoperatively did not shrink after 3–6 months of physical therapy (using elastic stockings, elastic bandages, etc.), and reflux could be observed by visual inspection or vascular ultrasound.

EHIT was evaluated as per the classification by Kabnick and Berland.<sup>4)</sup> Postoperative complications were defined

**Table 1** Baseline characteristics of varicose vein surgery

	All patients	Group A	Group B
Number of patients	672	497 (74.0%)	162
Male:female	289:383	211:286	75:87
Mean age (range: 16–93)	66.5	66.9	65.6
Number of treated legs	816	642 (78.7%)	174 (21.3%)
Target vein			
GSV	724	566	158
ASV	12	11	1
SSV	163	148	15
Treated side			
Bilateral	279	165	71
Right side	201	176	42
Left side	192	156	49
CEAP classification: clinical sign			
C2	816	642	174
C3	94	61	33
C4a	158	76	82
C5	8	3	5

GSV: great saphenous vein; ASV: accessory saphenous vein; SSV: small saphenous vein

as non-EHIT cases that required long-term follow-up lasting more than 1 month or pharmacological/invasive treatment, and applicable cases were extracted.

Statistical analysis was performed by Fisher’s exact test, and the significance level between-group comparisons was set at  $p < 0.05$ .

According to the common protocol, preoperative operations, including ultrasound, were completed on an ambulatory basis. For RFA, the ClosureFAST procedure comprising an endovenous RFA catheter (shaft diameter: 7 Fr.) and a closure RFG generator was employed. Patients were discharged after an ultrasound examination conducted the following day. The patients were recommended to wear either elastic bandages or elastic stockings for approximately 2 weeks after surgery, after which wearing was either continued or discontinued depending on their symptoms or their wishes. As a postoperative examination, the patients were interviewed, visually inspected, and palpated 1 day, 1 week, 1 month, and 3–6 months after surgery either in the hospital ward or the outpatient department. For postoperative evaluation, ultrasonography was performed either at the bedside or in the infirmary.

## Results

Group A included 17 legs with recurrence (2.65%), 43 legs with retention (6.70%), 24 legs with EHIT (3.74%), and

**Table 2** Postoperative conditions of radiofrequency ablation

	Group A	Group B	p-Value
Number of patients	497	162	
Gender (male:female)	211:286	75:87	
Mean age (range: 19–93)	66.9	65.6	
Number of treated legs	642	174	
Recurrence	17 (2.65%)	3 (1.72%)	0.481
Remnants	43 (6.70%)	14 (8.05%)	0.535
EHIT	24 (3.74%)	7 (4.60%)	0.862
Other complications	19 (2.96%)	3 (1.72%)	0.478

EHIT: endovenous heat-induced thrombosis

**Table 3** Postoperative recurrence of radiofrequency ablation

	Group A	Group B	p-Value
Number of patients	497	162	
Gender (male:female)	211:286	75:87	
Mean age (range: 19–93)	66.9	65.6	
Number of treated legs	642	174	
Recurrence	17 (2.65%)	3 (1.72%)	0.481
GSV	9 (1.40%)	3 (1.72%)	
ASV	1 (0.16%)	0 (0%)	
SSV	7 (1.09%)	0 (0%)	

GSV: great saphenous vein; ASV: accessory saphenous vein; SSV: small saphenous vein

19 legs with postoperative complications (2.96%). Meanwhile, Group B included 3 legs with recurrence (1.72%), 14 legs with retention (8.05%), 7 legs with EHIT (4.60%), and 3 legs with postoperative complications (1.72%). Between these two groups, no statistically significant differences were noted in the incidences of recurrence, complications, etc. (Table 2).

In Group A, the site of recurrence was the great saphenous vein (GSV) in 9 legs, the accessory saphenous vein (ASV) in 1 leg, and the small saphenous vein (SSV) in 7 legs. Of these, 3 legs (GSV: 2 legs, SSV: 1 leg) concomitantly developed EHIT. The mean period until recurrence was 16.8 months (min. 6 months, max. 4 years). The types of recurrence were partial patency in 4 legs, ASV reflux in 1 leg, Boyd's perforator reflux in 1 leg, Cockett's perforator reflux in 3 legs, superficial vein/incompetent communicating branch reflux in 3 legs, and SSV reopening in 5 legs. The therapeutic strategies after recurrence were re-RFA for 3 legs (GSV: 1 leg, SSV: 2 legs), sclerotherapy for 2 legs, and follow-up for 12 legs. The primary cause of all three recurrences in Group B was reflux from a perforating branch. The perforating branch was surgically ligated for 1 case, whereas the other 2 cases were followed up and went into remission (Table 3).

In Group A, the site of retention was the GSV in 40 legs, the ASV in 1 leg, the SSV in 0 legs, and an unknown site in 2 legs. Overall, 2 cases were complicated by EHIT, and

**Table 4** Postoperative remnants of varicose veins after radiofrequency ablation

	Group A	Group B	p-Value
Number of patients	497	162	
Gender (male:female)	211:286	75:87	
Mean age (range: 19–93)	66.9	65.6	
Number of treated legs	642	174	
Remnants	43 (6.70%)	14 (8.05%)	0.535
GSV	40 (6.23%)	5 (2.87%)	
ASV	1 (0.16%)	5 (2.87%)	
SSV	0 (0%)	3 (1.72%)	

GSV: great saphenous vein; ASV: accessory saphenous vein; SSV: small saphenous vein

**Table 5** EHIT after radiofrequency ablation

	Group A	Group B	p-Value
Number of patients	497	162	
Gender (male:female)	211:286	75:87	
Mean age (range: 19–93)	66.9	65.6	
Number of treated legs	642	174	
EHIT	24 (3.74%)	8 (4.60%)	0.862
Class I	16 (2.49%)	4 (2.30%)	
Class II	8 (1.25%)	3 (1.72%)	
Class III	0 (0%)	1 (0.57%)	
Class IV	0 (0%)	0 (0%)	

EHIT: endovenous heat-induced thrombosis

1 case had a hematoma in the GSV puncture site, which caused surgery to be discontinued. While no re-RFA operations were performed, sclerotherapy and follow-up were conducted for 12 and 29 cases, respectively, as an additional treatment. In Group B, all cases except one with an unknown site (GSV: 5 legs, ASV: 5 legs, SSV: 3 legs) were observed to have achieved remission in follow-up (Table 4).

In Group A, EHIT was observed in the GSV in 20 legs, the ASV in 0 legs, and the SSV in 4 legs. There were 16 cases of Class I, 8 cases of Class II, and 0 Class III/IV cases. One case was aggravated from Class II to Class III 1 month after surgery, and the patient required hospitalized care. However, the condition dissipated only with heparin instillation 5 days after remission, and the patient required no additional treatment. In Group B, EHIT was observed in 8 cases (Class I: 4 cases, Class II: 3 cases, Class III: 1 case, and Class IV: 0 cases). However, in both Groups A and B, all EHIT cases were naturally dissipated after the Class I patients were followed up and the Class II patients were treated with direct oral anticoagulants (DOAC) (Table 5).

The complications in Group A were lower limb phlegmon in 3 legs, sensory abnormality in 8 legs, thrombophlebitis in 2 legs, persistent pedal edema in 2 legs, and intraoperative GSV thrombosis that caused surgery to be discontinued in 1 leg. In Group B, there was 1 case of

delayed discharge due to intraoperative nausea/deconditioning, 1 case of hypesthesia, and 1 case of postoperative same-day hemorrhage from a high ligation site in the inguinal area.

## Discussion

Guidelines are conflicting regarding the effectiveness of combining phlebectomy and/or sclerotherapy for collateral varicose veins in the lower thigh during ETA; hence, this combined procedure has not been recommended yet. Major factors for this might be that randomized comparative studies are statistically biased and impracticable and that various developmental/running morphologies of lower-limb veins are anatomically difficult to explain unitarily. Moreover, it is also difficult to predict the reflux model associated with prolonged operative duration, increased complications, and postoperative relapses.

Since the initial introduction of RFA in our department, we have emphasized shortening the operative duration and providing less invasive surgery and aimed to perform single RFA operations as much as possible. When the patient opted, when the expansion of collateral veins with complex morphology was noted, or when shallow, superficial varicose veins ran over a fascia unsuitable to RFA, we also simultaneously excised collateral varicose veins. Procedures such as ligation of incompetent perforating branches were not performed in both Groups A and B. Since some cases were incomplete as pre- and postoperative observation or vascular ultrasonography records, they were excluded from the study items in this paper. Since sclerotherapy can be easily performed postoperatively on an ambulatory basis, it was implemented only minimally during RFA surgery. It was reserved as a postoperative therapy in line with the patient's consent/preferences. Therefore, as shown in **Table 2**, the incidences of respective events in Group A were well within the acceptable range as compared with those in Group B. The fact that no events necessitating a hospital visit occurred for 6 months after surgery except for remote-phase recurrences may prove that combined surgery may not necessarily be essential.

In Group A, most recurrent cases experienced reopening from collateral branches of the GSV, whereas the main cause in Group B was reflux from perforating branches. Consequently, single RFA operations yielded acceptable results. However, it was also true that the difference in the recurrence rates between Groups A and B was not negligible. Possible effective measures included performing preoperative ultrasonography to thoroughly check collateral and perforating branches, intraoperatively fully cauterizing the same site, or ligating the perforating branches as necessary. Since the reopening of the main trunk is more likely

to occur than reflux from collateral branches in the ASV and SSV, fully cauterizing the proximal side closer to the saphenous femoral vein junction should be considered for the ASV. A high-level ligation combined procedure<sup>5)</sup> is also regarded as effective for the SSV. In recent years, we have adopted the Venaseal Closure System, which inflicts no nerve damage by cauterization, for treating the SSV region. Alternatively, it was possible for patients with recurrence to be managed by assiduous follow-up using elastic bandages/stockings. However, because elastic bandages/stockings have various limitations, such as wearing frequency, sense of use, and size selection, their continued usage requires the awareness and cooperation of the patient.

Most retention patients were asymptomatic and did not actively seek medical attention. Accordingly, most patients went into remission after achieving an improvement in subjective symptoms and the shrinkage of varicose veins in follow-up. Sclerotherapy was only performed for patients who opted for additional treatment. Although excluded from the evaluation items in this study, BMI and saphenous vein diameter were indicated to be risk factors for the reopening of saphenous veins. Therefore, these factors should be assessed in future studies.<sup>6)</sup>

Except for one patient in Group A who was re-hospitalized after EHIT aggravated from Class II to Class III 1 month after surgery due to DVT and peripheral pulmonary embolism, no EHIT patients up to Class II experienced any aggravation and were treated with DOAC ingestion and careful ambulatory follow-up, and their condition was naturally dissipated within about 1 month after surgery. The exact cause of EHIT in the 1 patient in Group A who was re-hospitalized is unknown. The activity level of this patient was originally only walking indoors. Day surgery was performed at the strong request of the patient, and decreased activity at early and middle postoperative stages might have been one factor for the aggravated condition. In patients at risk of decreased activity in daily living, the use of elastic bandages/stockings was considered, with the patients encouraged to make efforts to wear them. This brought home the importance of proper exercise in daily living and selecting appropriate cases. Meanwhile, various postoperative complications originate from surgical procedures. In particular, caution is advised when introducing RFA and training specialized surgeons. Although it is a basic principle, it is of utmost importance to comply with the relevant guidelines and implementation protocols regarding cleaning procedures, protective techniques, and TLA anesthesia.

In previous references, Schanzer<sup>7)</sup> reported that performing ETA without any combined surgery resulted in the partial shrinkage and disappearance of collateral varicose veins around 1–3 months after surgery. Although not limited to single RFA surgery, Spiliopoulos et al.<sup>8)</sup>



reported that the reopening rate 1 year after RFA surgery was 12.1%. In a 5-year prospective study conducted in the West, the remote-phase recurrence rate was around 20%–30%, and the re-surgery rate was almost at the same level. Although not many reports are available, Japan's middle-period recurrence rate and re-surgery rate remained at very low levels, ranging from 0% to 2%. This study's rate was 2.65%, which was within the acceptable range. Although no reports have been available on retention rates, Kurihara et al. reported that the retention rate of EHIT in RFA cases was 2.7% for Classes II/III and 0% for Class IV. In our study, the EHIT retention rate in single RFA cases was 1.25 for Class II and 0% for Classes III/IV, which were comparable results.<sup>9–14)</sup>

The results of this study revealed that a single RFA surgery could yield sufficiently acceptable results. Nevertheless, given the variability of the follow-up periods for the patients, further careful follow-up observation will be required to reach a comprehensible conclusion about the remote period. Moreover, no interviews or follow-up surveys on the satisfaction of patients and pathological conditions in the remote period were implemented. There is room for consideration. Since our hospital is a private medical institution that plays a pivotal role in the east bank central area of Lake Biwa, patients seeking medical attention for problems or specific issues first visit or they are referred to our department. This environment is advantageous for conducting follow-up surveys. Almost no patients revisited our department with any problems or complaints 5 years after lower-limb varicose vein surgery. However, because impressions and perceptions vary from one patient to another, we cannot assert that all patients have been satisfied with our treatment. In light of the rising medical expenses and aging population, it makes medical and economic sense to aim to mitigate the burdens of additional medical care. Considering the esthetic preferences of patients, we assumed that it would be preferable to perform additional combined therapy for collateral varicose veins, incorporating full cauterization for the temporary closure of branching and reflux prediction based on detailed vascular ultrasonography. In addition, the occurrence rate of events requiring some additional treatment is considered to be small in ETA, and this low frequency is a statistical limitation in this study. Therefore, it would be possible to both develop more effective modalities and improve patient satisfaction by investigating various cases, including recurrences and retentions not only at our hospital but also in multicenter joint studies, etc.

## Conclusion

In treatment for varicose veins of lower extremities, ensuring safety and low invasiveness is the absolute requirement.

Another aspect is an esthetic demand (of wanting to “look good”); hence, surgical outcomes need to be pleasing to the eyes of the patients themselves and the people around them. The results of this study indicated that single RFA surgery is enough to achieve the goal of treating varicose veins. However, it is also important to consider combining phlebectomy, sclerotherapy, etc., within the allowable range. Along with performing temporary reflux prevention, aiming to prevent the re-expansion of retained varicose veins will contribute to ameliorating symptoms at an early stage and improving remote-phase outcomes and patient satisfaction. In addition to conducting further case studies, alleviating symptoms in patients, and resolving esthetic complaints, it is essential to establish minimally invasive, recurrence-free, and effective therapeutic strategies requiring few additional therapies that could contribute to the medical economy and hospital management.

## Disclosure Statement

All authors of this article have no conflicts of interest to disclose.

## Notes

This article concerns a clinical study approved by the ethics review committee of our hospital (approval no.: 2021-10).

## References

- 1) Hirokawa M, Satokawa H, Yasugi T, et al. Clinical practice guidelines for endovenous thermal ablation for varicose veins 2019. *Jpn J Phlebol* 2019; 30 Supple: i–81. (in Japanese)
- 2) Eklöf B, Rutherford RB, Bergan JJ, et al. Revision of the CEAP classification for chronic venous disorders: consensus statement. *J Vasc Surg* 2004; 40: 1248–52.
- 3) Satokawa H, Sugiyama S, Hirokawa M, et al. Guidelines for endovenous treatments for varicose veins. *Jpn J Phlebol* 2010; 21: 289–309. (in Japanese)
- 4) Kabnick LS, Berland T. Heat induced thrombosis of the femoral vein after endovenous ablation for the great saphenous vein: clinical relevance? Best practice in venous procedures (Wittens C, ed), Edizioni Minerva Medica, Torino, Italy, 2010, 111–116.
- 5) Sato K, Emura S, Morita S. Treatment for small saphenous-type varicose veins with endothermal ablation incorporating high ligation of the saphenopopliteal junction. *J Jpn Coll Angiol* 2018; 58: 55–60. (in Japanese)
- 6) Lomazzi C, Bissacco D, Logan SM, et al. Risk factors for saphenous vein recanalization after endovenous radiofrequency ablation. *J Cardiovasc Surg (Torino)* 2021; 62: 427–34.
- 7) Schanzer H. Endovenous ablation plus microphlebectomy/sclerotherapy for the treatment of varicose veins: single or

- two-stage procedure? *Vasc Endovascular Surg* 2010; **44**: 545–9.
- 8) Spiliopoulos S, Theodosiadou V, Sotiriadi A, et al. Endovenous ablation of incompetent truncal veins and their perforators with a new radiofrequency system. Mid-term outcomes. *Vascular* 2015; **23**: 592–8.
  - 9) Woźniak W, Kielar M, Mlosek KR, et al. Comparative analysis of five-year outcomes of lower extremity varicose vein therapy using monopolar and segmental radiofrequency ablation. *Int Angiol* 2018; **37**: 457–64.
  - 10) Utoh J, Tsukamoto Y. Long-term clinical results after endovenous thermal ablation for primary varicose veins: a comparative study to stripping surgery. *J Jpn Coll Angiol* 2021; **32**: 105–10. (in Japanese)
  - 11) Nakamura K, Murayama T, Endoh H. Study of the treatment results of radio frequency ablation for varicose veins in Kannai Medical Clinic. *Jpn J Phlebol* 2017; **28**: 17–22. (in Japanese)
  - 12) Shimizu T. Three-year results of endovascular laser ablation of great and small saphenous vein in patients with varicose veins. *Jpn J Phlebol* 2018; **29**: 419–25. (in Japanese)
  - 13) Kurihara N, Hirokawa M, Yamamoto T. Postoperative venous thromboembolism (VTE) in patients undergoing endovenous laser and radiofrequency ablation of the saphenous vein. *J Jpn Coll Angiol* 2015; **55**: 153–61. (in Japanese)
  - 14) Kheirleiseid EHA, Crowe G, Sehgal R, et al. Systematic review and meta-analysis of randomized controlled trials evaluating long-term outcomes of endovenous management of lower extremity varicose veins. *J Vasc Surg Venous Lymphat Disord* 2018; **6**: 256–70.